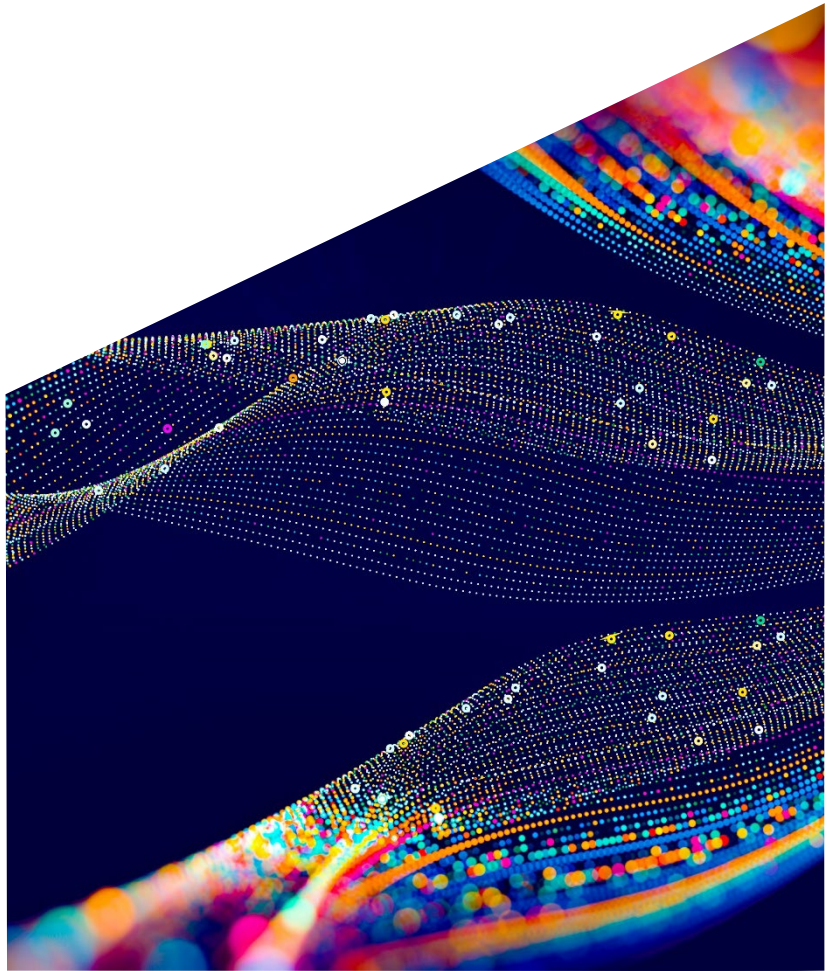
McDermott Will & Emery

KoBIA
Korea Biomedicine Industry Association
한국바이오의약품협회

Essentials of Global Market Entry Planning – An Introduction



Webinar with the Korea Biomedicine Industry Association

July 24, 2023

Sharon Lamb, Partner

Peter Lu, Partner

Michael G. Morgan, Partner

Siddhartha Sivaramakrishnan, Partner

Speakers

SHARON LAMB
Partner, McDermott
slamb@mwe.com
London
+44 20 7577 6943

MICHAEL G. MORGAN
Partner, McDermott
mmorgan@mwe.com
Los Angeles, Silicon Valley
+1 310 551 9366

PETER LU
Partner, McDermott
plu@mwe.com
London
+44 20 3139 1581

SIDDHARTHA SIVARAMAKRISHNAN
Partner, McDermott
siddharthas@mwe.com
Singapore, London
+65 9772 3250

Agenda

1. Operations/Risk Management
2. Key Legal Challenges
3. General Contracting and Licensing
4. Navigating Common Pitfalls

US Operations Structure & Government Incentives

- **Basic – Form a US corporate subsidiary**
- **Adjustments to US legal system**
- **Incentives can be for:**
  - Job creation
  - R&D
  - Capital expenditures
  - Workforce training
- **Incentives can take the form of:**
  - Tax rebates/credits
  - Grants
  - Low-cost financing
  - Expedited permitting

Employment, Benefits, Compensation

- **Expectations as an employer and as a business**
- **Compensation**
- **Work visas/Immigration**

Risk Management for Operations

- **Mandatory insurance**
  - Workers' compensation

- **Optional insurances**
  - General liability
  - Property/casualty
  - Products liability
  - Directors and officers

  - Policies can be added via "riders" on existing foreign policies

Intellectual Property

- **Design and implement an exclusivity strategy**
  - IP attorney as architect, not mechanic
  - Align dealmaking with IP strategy
  - Collaborations vs out-licensing?

- ***Road Map:***
  - 1st – FTO: Freedom to operate without 3rd party conflict?
  - 2nd – Is IP portfolio differentiated?
  - 3rd – Is IP configured for commercialization?

Regulatory Effects on Dealmaking

- **Align regulatory (FDA) strategy with reimbursement strategy**
- **Consider trade compliance** – tariffs on imports, USA export licensing rules, etc.
- **Plan for multiple other regulatory rules**
  - Antitrust – for example, FTC approval required for M&A, some pharma patent licenses, etc.
  - CFIUS

Legal and Business Challenges

- **Manufacturing and importing issues**
  - Complying with FDA product requirements
  - Anticipating and preparing for distribution challenges
- **Investment issues**
  - Understanding US Merger & Acquisition requirements and practices
- **Tax issues**
- **Dispute resolution**

Data Privacy and Protection

- **Application of HIPAA & state privacy laws**
  - Medical and trial data may be subject to different requirements under federal and state laws
- **Appropriate Security Practices**
  - US state laws require “reasonable security” and contain certain obligations in the event of a data breach
- **Data Transfers**

CFIUS – Foreign Investment Approval

- **CFIUS** – **Committee on Foreign Investment in the US** – can affect several types of cross-border transactions:
  - M&A
  - Controlling and non-controlling investments
  - Some licenses
- **Process:**
  - File a “Voluntary Notice”
  - And/or file a “Mandatory Declaration”
  - Plan for 60-90 days, and in some cases longer
- **Possible consequences of non-filing:** Unwinding or divestiture of transaction, and penalty

Global Expansion: Considerations for EU and UK Market Entry

- **Align FDA strategy with market authorizations in other jurisdictions**
  - Global clinical trials: understand the evidential requirements of global authorities
  - Real world evidence: determining the standards and guidance for market entry and real world evidence

- **Market Authorisations**
  - EMA – EU wide authorization
  - National authorizations
  - UK – understand the ability to accept EU authorizations and UK timelines

Global Expansion: Considerations for EU and UK Market Entry

- **Medical Device strategy**
  - EU MDR – the EU wide regulation for medical devices
  - UK Medical device regulation – based on the prior EU regulation
  - Classification of devices
  - Notified bodies

- **Reimbursement**
  - Unlike authorizations and certifications, reimbursement is national

- **Data Protection**: When developing US and global data protection, consider GDPR in building data protection compliance, policies and transferring mechanisms

The UK's National Security and Investments Act

- **Synthetic biology is captured by NSIA**
  - Synthetic biology is the process of applying engineering principles to biology, to design, redesign or make biological components or systems that do not exist in the natural world: in other words, designing biological systems that do not exist in nature
- **A mandatory filing is required**
  - With a stand-still obligation until clearance is obtained, if the buyer acquires control or >25% of the shares or voting rights of the target
- **Sanctions for not filing**
  - Suspending a transaction during its review or requiring a transaction to be unwound following its review. Penalties for failure to comply are imprisonment (up to 5 years) and/or fines (the higher of 5% of global turnover or £10m)

General Contracting

- **Be prepared to implement ordinary-course commercial contracts:**
  - Customer facing: T&Cs for purchase/sale of goods/services
  - Commercial partner facing: Distribution, supply and representative agreements
  - Industry specific agreements: e.g., contract manufacturing, clinical trial agreements, etc.

Licensing

- **Know the market trends.**
- **Define purpose.** Collaborate? Exit or financing opportunity? Spinout?
- **Typical issues** – governance/JSC, licensee's commercially reasonable efforts (CRE), IP ownership (esp. in collaborations)
- **Grant** – scope, exclusive/not, sublicensable (etc.), licensor's retained rights and grant-backs, consistency with obligations to 3rd parties, etc.
- **Types of payment** – upfront, development, commercial, royalties, term, etc.

Navigating Common Pitfalls

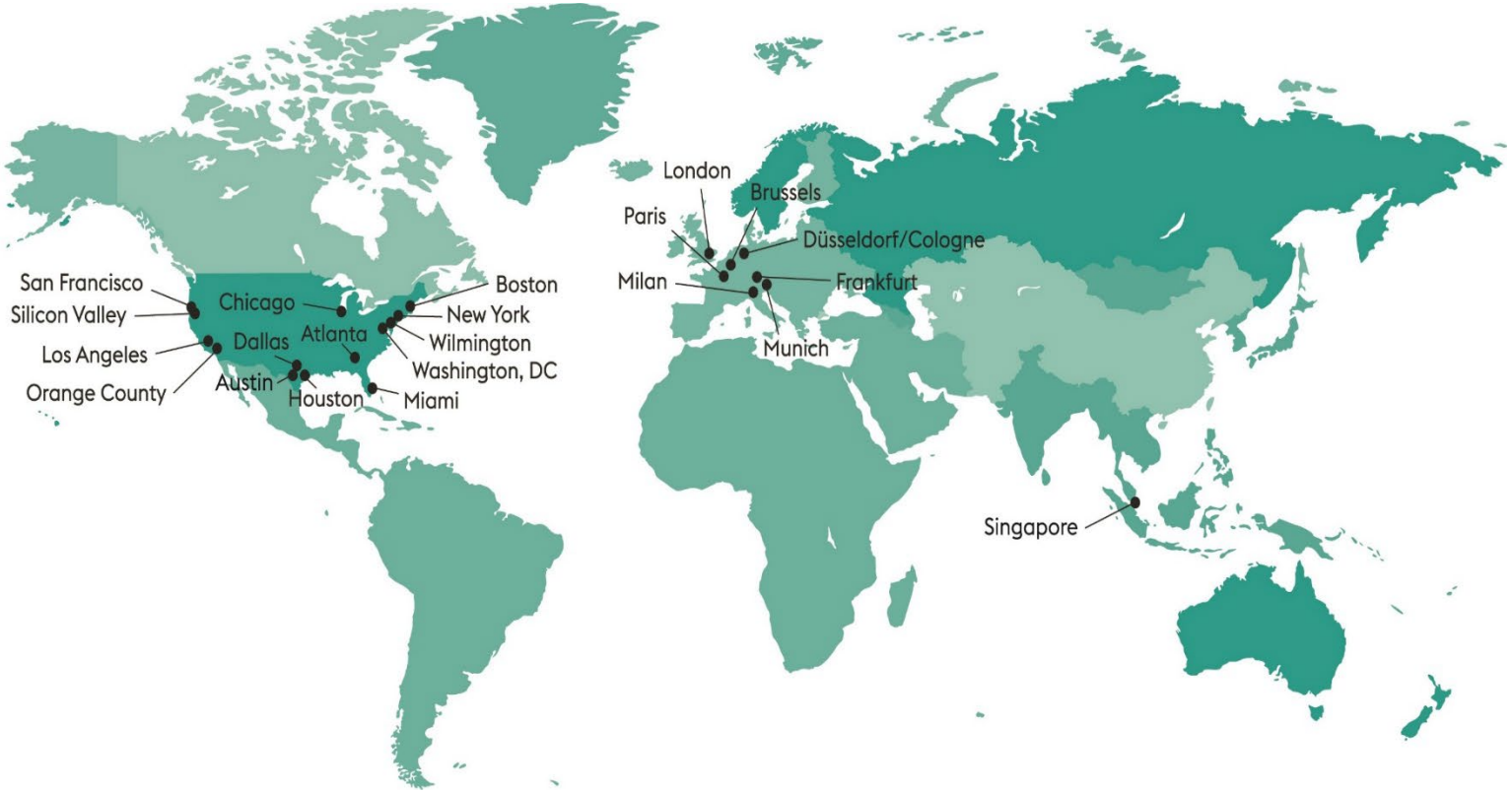
- **Federal Trade Commission (FTC) Act**
  - Prohibits unfair or deceptive practices
- **Patchwork compliance requirements**
  - Activities are subject to the laws and regulations of one federal regime and 50 state regimes
- **Understanding Enforcement Patterns**
  - Risk levels & penalties vary with priorities and resources

ABOUT McDERMOTT

20+ LOCATIONS

1,200+ LAWYERS

100+ COUNTRIES SUPPORTED



Best Lawyers LAW FIRM OF THE YEAR U.S.News & WORLD REPORT HEALTH CARE LAW 2022

Chambers RANKED IN Global 2023 Leading Firm

RANKED IN Chambers USA 2023

RANKED IN Chambers Europe 2023

Chambers RANKED IN Asia-Pacific 2023 Leading Firm

ACCOLADES

Ranked Nationwide in **Life Sciences** - *Chambers USA* 2022

French, German and UK teams ranked in **Healthcare and Life Sciences** - *Legal 500* and *Chambers* 2022

Highly Recommended for **Healthcare: Pricing & Reimbursement** - *LMG Life Sciences* 2022

Represent **75% of the top 20** biopharmaceutical companies globally

Ranked Nationwide in **Healthcare: Life Sciences** - *Legal 500 USA* 2022

Recognized for **FDA: Medical Device** - *LMG Life Sciences* 2022

Ranked in **Healthcare: Pharmaceutical/ Medical Products Regulatory** - *Chambers USA* 2022

35% of our life sciences lawyers hold **advanced degrees in life sciences fields**

Q&A

SHARON LAMB
Partner, McDermott
slamb@mwe.com
London
+44 20 7577 6943

MICHAEL G. MORGAN
Partner, McDermott
mmorgan@mwe.com
Los Angeles, Silicon Valley
+1 310 551 9366

PETER LU
Partner, McDermott
plu@mwe.com
London
+44 20 3139 1581

SIDDHARTHA SIVARAMAKRISHNAN
Partner, McDrmott
siddharthas@mwe.com
Singapore, London
+65 9772 3250